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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/643,755	08/23/2000	Gijs van Rooijen	9369-153/MG	1008
1059	7590	05/31/2007		
BERESKIN AND PARR 40 KING STREET WEST BOX 401 TORONTO, ON M5H 3Y2 CANADA			EXAMINER HELMER, GEORGIA L	
			ART UNIT	PAPER NUMBER
			1638	
			MAIL DATE	DELIVERY MODE
			05/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/643,755

Applicant(s)

VAN ROOIJEN ET AL.

Examiner

Georgia Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-17 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-17 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 March 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Office Action

1. Applicant's submission filed on 20 March 2007 is acknowledged. The C.F.R. § 1.132 declaration of Brent Pollock dated 18 March 2007 is acknowledged.

Status of the Claims

2. Applicant has amended claims 1 and 17. Claims 1, 3, 5-17, and 21 -23 are pending, and are examined in the instant action.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

5. Claims 1, 3, 5-17 and 21-23 are rejected under 35 U.S.C. 103 as being unpatentable over Willmitzer et al (WO 92/01042) in view of Kusnadi, et al., 1998, (Biotech. Bioeng, Vol 60, No. 1, pages 44-52) and Applicant's admitted prior art, for reasons as set forth in the Office Action of 27 September 2006 as well as those below.

Claims 1 and 17 have been amended to specify that the chymosin is "biologically active" and that the grinding is in "water or buffer".

Applicant traverses primarily the method used in Kusnadi, et al. would not be useful in isolating biologically active chymosin. (Response, p. 8, 1st ¶)

The C.F.R. § 1.132 Declaration of Brent Pollock

The C.F.R. § 1.132 Declaration of Brent Pollock dated 18 March 2007 concludes that "extraction from seed using hexane extraction and/or dry crushing destroys the

activity of the chymosin and therefore such a procedure would not be used in a manufacturing method for the isolation of chymosin in seed" (Declaration p. 3-4, ¶ 8).

However Pollock, in ¶ 5, demonstrates the when chymosin-containing seed were extracted with hexane prior to the normal aqueous extraction, it showed 31% of the activity detected for the positive control (non-hexane treated) extract. This means that when the claimed method of chymosin production produces 100% yield, addition of a hexane extraction step to the claimed method produced 31% chymosin activity. This demonstration is in stark contrast to Applicant's statement that extraction from seed using hexane extraction and/or dry crushing destroys the activity of the chymosin and therefore such a procedure would not be used in a manufacturing method for the isolation of chymosin in seed. *The chymosin protein activity recovery of 31% is NOT evidence for destruction of the activity of the chymosin.*

Unfortunately, the three figures included in the declaration are light and fuzzy, and of insufficient quality to evaluate the data thereof. New Figures of High quality copies of these figures are required for evaluation of this data. Otherwise these figures will not be evaluated, and will be given no weight.

Applicant traverses concluding that the dry crushing of seed prior to protein extraction destroys the activity of chymosin. (Declaration, ¶ 6 and 7).

These data would appear to indicate that Applicant's claimed method prior to the present amendment of claim 1 to include "in the presence of water or a buffer" would produce chymosin protein totally devoid of biological activity.

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Applicant's traversal is unpersuasive. Kusnadi, et al. teach the extraction of the seed fraction with aqueous phosphate buffer (Kusnadi, et al. p. 46, 1st column, final ¶ and 2nd column; see also Figure 2, p. 46 describing the purification).

Therefore Applicant's traversal are unpersuasive.

Remarks

6. No claims are allowed


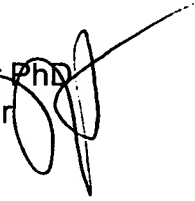
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 10-6 Monday & Tuesday, 1-5 pm Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Georgia Helmer PhD
Patent Examiner
Art Unit 1638
24 May 2007



PHUONG T. BUI
PRIMARY EXAMINER